Dinal W. Y. Sah et al. Attorney Docket No. REGEN1610-1

In re Application of:
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Application No.: 10/813,203
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## REMARKS

Claims 12-17 and 33 are currently pending in the application. Claims 12, 16, and 33 are amended by the present communication. The subject amendments are supported by the specification at, for example, p. 14, ll. 2-5 and the claims as originally filed. No new matter is added by the present amendments. In view of these amendments, claims 13-15 are canceled herein without prejudice or disclaimer. It is respectfully submitted that the current amendments reduce the number of claims and place the remaining claims in condition for allowance or, at a minimum, in better condition for appeal. Accordingly, entry of the present amendments are respectfully requested. Upon entry of these amendments, claims 12, 16, 17, and 33 and will remain pending and under consideration.

## Rejection Under 35 U.S.C. §112, First Paragraph

Claims 12-17 and 33 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly not enabled by the specification. Applicants note that the rejection as applied to claims 13-15 has been rendered moot by the cancellation herein of these claims. Applicants traverse the rejection as applied to the pending claims, for the reasons of record and those that follow.

The Office Action alleges, in pertinent part, that the specification is not enabling because at the time of the invention, successful implementation of cell therapy protocols and ex vivo gene therapy protocols were not routinely achievable by those skilled in the art, citing several references in efforts to support this position. Without acquiescing to the reasoning offered in the Action, and in order to reduce the issues and expedite prosecution, claim 14 directed to a method of treating a subject has been canceled herein. Thus, the Examiner's concerns with regard the unpredictability of achieving a therapeutic effect by administration of the disclosed conditionally-immortalized CNS progenitor cells has been rendered moot.

Applicants submit that the claims as amended are fully enabled by the specification. The present invention, as defined by amended claim 12, is directed to methods for introducing differentiated CNS cells into a murine or primate by administering conditionally-immortalized In re Application of:
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CNS progenitor cells to the murine or primate and suppressing the production or activity of the growth-promoting gene, thereby inducing the CNS progenitor cells to differentiate into neurons and/or astrocytes. Applicants submit that the claims are enabled by the specification, which provides appropriate guidance to allow one of skill in the art could practice the invention as claimed. As discussed in the previous Response, the specification provides detailed examples demonstrating the preparation and characterization of conditionally-immortalized CNS progenitor cells (e.g., Example 1), as well as specific examples for the production of differentiated cells (e.g., Example 2). In addition, the specification provides guidance regarding compositions of such progenitor cells and routes of administration for delivery in vivo (see, e.g., p. 20, Il. 4-27).

Based on the foregoing, Applicants submit that the present claims are fully enabled by the present disclosure. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested. In re Application of:
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## CONCLUSION

Applicants submit that pending claims 12,16, 17, and 33 are in condition for allowance. The Examiner is invited to contact Applicants' undersigned representative if there are any questions relating to this submission.

No fee is deemed necessary with the filing of this paper. However, the Commissioner is hereby authorized to charge any fees required by this submission, or make any credits or overpayments, to Deposit Account No. <u>07-1896</u> referencing the above-identified attorney docket number.

Respectfully submitted,

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